REMARKS/ARGUMENTS

Claims 1-13 constitute the pending claims in the present application. Claims 1-6 were initially elected with traverse. Claim 7 is withdrawn from consideration as being drawn to a non-elected invention. However, Applicants point out that claim 7 depends from claim 1 and contains all the limitations thereof. Applicants respectfully direct the Examiner's attention to MPEP 809, which states that upon allowance of a generic linking claim, "[a]ny claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability." Reconsideration and reinstatement of claim 7 is respectfully requested in light of the above arguments should claim 1 be found allowable.

Claims 4-6 have been amended. Claims 8-13 have been added. No new matter is being introduced. Support for the claim amendments and the new claims is found in the specification and in the original claims. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Applicants note that the Examiner has acknowledged Applicants' election of Group I (claims 1-6) in Paper No. 12, and has entered the Preliminary Amendments filed in Paper Nos. 5 and 8.

Claim Objections

Claim 6 is objected to because the Office Action asserts that each claim must be expressed as a complete sentence. As the Examiner requested, Applicants have amended claim 6. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

Claim rejections under 35 U.S.C. 112, first paragraph

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

Particularly, the Office Action asserts that "the engineered cell of the claims encompasses a genus of any and all cells of all kingdoms, genera and species engineered by any and all means to have the phenotypic limitations of the claims." The Office Action further asserts that "the specification provides two strains of S. cerevisiae (i.e., lcb1/SLC-1 and lcb1/pGPD-SLC-1)," and "these disclosed species are not representative of the full scope of the genus."

Applicants submit that, pursuant to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, §1, "[t]he written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus."

Claims 1 and 2 satisfy the written description requirement. For example, the claims recite the cells' functional characteristics coupled with a known or disclosed correlation between function and structure. In addition, the specification amply teaches that cells comprising an lcb1 allele and an SLC1-1 gene, whose capability to synthesize sphingolipids depends on the addition of exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids, can be used in the claimed screening assay (see, e.g., Examples 1-2; pages 3-6). Accordingly, the specification provides both working examples and sufficient description of these functional characteristics that are coupled with correlation between function and structure of the cells. Based on the teachings of the specification, one skilled in the art would reasonably conclude that Applicants had possession of the invention as claimed in claims 1 and 2 at the time of filing. For the reasons presented above, Applicants submit that all pending claims as amended fully comply with the written description requirement. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph, are respectfully requested.

Claim rejections under 35 U.S.C. 112, first paragraph

Claims 1-3 and 5-6 are rejected under 35 U.S.C. 112, first paragraph, because of alleged non-enablement. Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

Regarding claims 1-3, the Office Action asserts that "the specification, while being enabling for an engineered S. cerevisiae comprising the lcb1/SLC1-1 genotype and further over-expressing SLC-1, and a method identifying a selective IPC synthase inhibitor using said engineered S. cerevisiae, does not reasonably provide enablement for any and all cells having the phenotype of exogenous phytosphingosine dependent sphingolipid synthesis and ability to grow via compensatory phospholipids or methods of identifying IPC synthase inhibitors using any and all cells having that phenotype" (see Office Action, page 6, lines 11-17).

Applicants submit that the specification sufficiently enables one skilled in the art to practice the invention of claims 1-3. The Examiner contends that the claims relate to any engineered cells. This is not the case, and it is clear in the specification that such cells must be able to function as a host for a fungal IPC synthase. The specification teaches that "[a]ny convenient host cell strain may be used provided that it can function as a host for a fungal IPC synthase gene" (e.g., page 2, lines 12-13). Furthermore, the specification describes other cells besides S. cerevisiae that may be used in the practice of the invention. For example, the specification teaches that "[c]onvenient hosts include fungi that are manipulatable genetically such as S. cerevisiae but also others such as Candida albicans, Candida glabrata, Aspergillus sp. or Schizosaccharomyces pombe" (e.g., page 2, lines 12-17). The Examiner refers to a particular S. cerevisiae strain that is not robust enough for screening purposes. However, the specification discloses how such a problem can be overcome. For example, the specification illustrates that "[a] convenient host strain for use in the assay methods of the invention is an lcb1/ SLC1-1 strain...Adapting host cells for sustained growth is for example achieved by enhancing expression of the compensatory mutant SLC1-1 allele" (e.g., page 3, lines 3-20). Accordingly, Applicants submit that claims 1-3 satisfy the enablement requirement under 35 U.S.C. 112, first paragraph, and respectfully request reconsideration and withdrawal of this rejection.

Regarding claims 5-6, the Examiner asserts that "the claims are directed to the specifically named S. cerevisiae strain (lcb1/pGPD-SLC-1) or further engineered strains of S. cerevisiae (lcb1/pGPD-SLC-1)... Although the strain is described in the specification, no evidence is provided that would indicate that it is readily available to the public. Without such availability, practicing the invention is impossible and the claims are therefore not enabled" (see Office Action, page 9, lines 2-8). The Examiner further suggests that this rejection can be traversed by perfecting a deposit of the S. cerevisiae (lcb1/pGPD-SLC-1) strain according to the rules for deposit of biological material.

Applicants submit that the specification sufficiently teaches how to make and use the S. cerevisiae (lcb1/pGPD3-SLC1-1) strain in a reproducible manner (e.g., Example 1, page 3-6). Given the detailed teachings of the specification and the knowledge in the art, one skilled in the art could readily make and use the lcb1/pGPD3-SLC1-1 yeast strain without undue experimentation. Further, the specification teaches that the GPD3 promoter is an example of a very strong constitutive promoter in S. cerevisiae. "Other glycolytic enzymes such as Phosphoglycerate Kinase (PGK), Enolase I (ENO), Pyruvate Kinase (PYK) and Fructose-Bisphosphate Aldolase 11 FBA are convenient sources of other such promoters" (e.g., page 3, lines 15-18). Accordingly, Applicants submit that claims 5-6 satisfy the enablement requirement under 35 U.S.C. 112, first paragraph, even without a deposit of the S. cerevisiae (lcb1/pGPD3-SLC1-1) strain.

Based on the above arguments, Applicants submit that all claims as amended comply with the enablement requirement of 35 U.S.C. 112, first paragraph. Therefore, reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945.**

Respectfully Submitted,

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